UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,492	08/18/2000	Gary Van Nest	377882000800	7136

7590 04/23/2002

KAREN R. ZACHOW, PH.D.
MORRISON & FOERSTER LLP
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/23/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/642,492	Applicant(s) VAN NEST ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,11-23,25-33 and 37-52* is/are pending in the application.

4a) Of the above claim(s) *43-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-33 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant has cancelled claims 2, 3, 7-10, 24 and 34-36, amended claims 1, 4-6, 11, 12, 22, 25, 26, and 37, and added new claims 38-52. Claims 1, 4-6, 11-23, 25-33 and 37-52 are under consideration.

Election/Restrictions

Newly submitted claims 43-52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 43 and 44 are drawn to a method of treating an allergy in an individual. This method requires the administration of different ingredients from the originally presented method and composition claims, i.e., an immunostimulatory sequence and a first allergen and second allergen. In addition, claims 43 and 44 are drawn to treating a disorder, while the originally presented method and composition claims are directed to modulating an immune response to a second antigen. These methods are directed to different goals and outcomes. The methods also involve different subjects. The subjects treated in claims 43 and 44 are required to suffer from allergies, while the subjects of the original method are not required to have any disorder.

Claims 45-52 are drawn to a method of vaccinating individuals against any disease. The goal of this method requires a prophylactic and ameliorating immune response to be elicited against any pathogenic agent, which is a completely different goal from the original method of modulating an immune response to a second antigen.

Finally, a search for the newly presented methods is not coextensive.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 43-52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 6, 11-13, 14, 17, 20-23, 25-33 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (WO 98/55495, "Schwartz") for reasons of record.

Newly presented claims 40-42 are drawn to a composition comprising an immunostimulatory polynucleotide (ISS) composition proximately associated with a first antigen that is an allergen, Amb a 1, and a second antigen.

Schwarz teaches an immunomodulatory composition comprising an ISS conjugated to AgE, also known as amb a1, page 30, lines 19 and 20 and page 31, lines 10-13, claims 25, 27 and Figure 7. Schwarz also teaches administering the ISS conjugates in the same location on or in the patient, see page 24, line 23 to page 26, line 33 and at different locations, depending on the particular immune response to be elicited, see page 26, line 34 to page 27, line 4. Although Schwartz does not explicitly teach administering a second antigen with the composition, Schwartz teaches that the immunomodulatory compositions comprise at least one antigen, see page 5, lines 1-2 and page 12, lines 9-15. Therefore, administering a second antigen would be an obvious variation to the teachings of Schwartz.

Applicant argues that Schwartz does not disclose modulation of an immune response to a second antigen in response to administration of a first antigen linked to an immunomodulatory polynucleotide (ISS).

Applicant's arguments as well as a review of the reference have been considered, but are found unpersuasive. Schwartz teaches that ISS oligonucleotides are art-recognized as being Th1 stimulatory molecules when administered with an antigen, see page 3, lines 32-35 and claims 47 and 48 of Schwartz recite inducing a Th1 response by co-administering an antigen conjugated to an oligonucleotide. As discussed above, Schwartz also teaches that the immunomodulatory compositions comprise at least one antigen, see page 5, lines 1-2 and page 12, lines 9-15. Therefore, although Schwarz does not explicitly teach administering more than one antigen in the composition the reference suggests doing so in order to elicit a Th1 response to every antigen administered with the ISS oligonucleotide. Therefore, administering a second antigen would be an obvious variation to the teachings of Schwartz. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to administer a second antigen in order to elicit a specific immune response against another portion of a pathogen or another strain of virus. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because Schwartz teaches that antigens administered with an ISS conjugate elicit a Th1 immune response. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent evidence to the contrary.

Claims 1, 4, 6, 11-13, 14, 17, 20-23, 25-33 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (WO 98/16247, "Carson").

With respect to newly presented claims 40-42, Carson teaches an immunomodulatory composition comprising an ISS conjugated to AgE, also known as amb a1, see page 19, line 22, and Figures 3-5. Carson also teaches administering the complex at the same location in or on the patient, see page 26, line 24 to page 29, line 6. Carson does not teach administering the compositions at different locations. However, the ordinary artisan may be motivated to administer the compositions through different routes depending on the patient's ailment or need. Although Carson does not explicitly teach administering a second antigen with the composition, Carson teaches that the immunomodulatory compositions comprise at least one antigen/ISS conjugate, see page 19, lines 1-7 for example. Therefore, administering a second antigen would be an obvious variation to the teachings of Carson. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to administer a second antigen in order to elicit a specific immune response against another portion of a pathogen or another strain of virus. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because Carson teaches that antigens administered with an ISS conjugate elicit a Th1 immune response. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent evidence to the contrary.

Applicant argues that Carson does not disclose modulating an immune response to a second antigen by administering a first antigen conjugated to an ISS molecule and does not anticipate the invention.

Applicant is persuasive with respect to Carson not explicitly teaching administering a second antigen. However, Carson suggests that the composition comprise more that one antigen,

see for example page 17, lines 5-10, page 19, lines 1-7, and claims 27 and 54. Therefore, although Carson does not explicitly teach administering more than one antigen in the composition the reference suggests doing so in order to elicit a Th1 response to every antigen administered with the ISS oligonucleotide. Therefore, administering a second antigen would be an obvious variation to the teachings of Carson.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al. as applied to claims 1-4, 6-8, 13, 14, 17, 20-36 above, and further in view of Rose (J. Ther. Biol. 1998; 195: 111-128) for reasons of record.

Claim 15 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al. and Rose as applied to claims 1-8, 13, 14, 17, 20-36 above, and further in view of Lee et al. (Ann Med. 1998; 30: 460-468) for reasons of record.

Claims 16 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al., and Rose, as applied to claims 1-8, 13, 14, 17, 20-36 above, and further in view of Durali et al. (J of Virol. 1998; 72(5): 3547-3553) for reasons of record.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al., Rose, Lee et al., and Durali et al. as applied to claims 1-8, 13-17, 20-36 above, and further in view of Anderson (US Patent 4,673,574) for reasons of record.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al., Rose, Lee et al., Durali et al., and Anderson as applied to claims 1-8 and 13-36 above for reasons of record.

Applicant argues that since the primary references of Schwartz and Carson do not teach or suggest the instant claims drawn to an immunomodulatory polynucleotide proximately

associated with a first antigen with a second antigen to modulate an immune response to the second antigen, and the secondary references do not remedy the primary references, a prima facie obvious case has not been established.

Applicant's arguments have been considered, but are found unpersuasive because while the primary references, Schwartz or Carson, do not explicitly teach administering a second antigen in the method or composition, the references suggest doing so. Further, both references teach that the oligonucleotide immunomodulatory sequences (ISS) induce a Th1 response specific to an antigen administered with the ISS. Therefore, administering a second antigen with the conjugate comprising a first antigen and an ISS would be an obvious variation to the teachings of Schwartz or Carson.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
April 11, 2002

James C. Housel 4/22/02
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600